REMARKS

Claims 1-19 appear in this application for the Examiner's review and consideration. In response to the Examiner's restriction requirement, applicants provisionally elect the invention of the Group I, claims 1-6 for prosecution in this application. Accordingly, applicants expressly reserve the right to file a divisional application for the claims of Group II (claims 7-19) prior to issuance of this application.

In addition, applicants respectfully request that the Examiner withdraw the restriction requirement so that Groups I-II are examined together. The claims in these groups are drawn to at least one poorly bioavailable drug dissolved in an effective amount of menthol and a method of improving the bioavailability of a drug by dissolving the drug in an effective amount of menthol.

Applicants elect the specie of drugs with low aqueous solubility which includes the statin drugs such as those recited in claim 5.

The Office states that the related inventions are distinct, citing MPEP § 806.05(h), however, this only underlines the Office's misunderstanding of the claims. The Office ignores the requirements of 806.05(h) that it must show that the inventions are distinct if: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process. See, MPEP 806.05(h). "The burden is on the examiner to provide an **example**, but the example need not be documented. *Id.* (emphasis added).

The Office proposes that a "composition containing cyclosporine and methanol can be used for the treatment of patients having undergone organ transplantation to prevent organ rejection." Office Action p. 2. The process must include menthol, not methanol, yet this distinction makes no difference in the analysis. If the composition is administered in the example provided by the Office, its effect is uniform and cannot be separate as suggested by the Office. The administration of cyclosporine and menthol for organ rejection will also improve the bioavailability of cyclosporine and these methods cannot be distinguished. Thus, the example provided by the Office is inapplicable.

Further, election of Group I (concerning the compositions) would necessitate a search of subject matter of Group II (concerning the method of using the compositions). All the groups are based upon the SAME composition. For this reason, the Examiner's distribution of claims in separate groupings is not based upon any undue searching burden, since the

subject matter of the other groups must be reviewed in order to determine whether the claims of Group I are patentable.

The M.P.E.P. § 803 states:

> If the search and examination of an entire application can be made without serious burden, the examiner >must< examine it on the merits, even though it includes claims to distinct or independent inventions (emphasis added).

Applicants respectfully remind the Examiner that every requirement to restrict has two aspects: (a) the reasons (as distinguished from the mere statement of conclusion) why the inventions *as claimed* are either independent or distinct; and (B) the reasons for insisting upon restriction therebetween. MPEP 808 (8th Ed. 2001). The particular reasons relied on by the Examiner for holding that inventions as claimed are independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. MPEP 816 (8th Ed. 2001).

There is no "serious burden" in this search, because all groups of claims are classified in the same class and subclass 514/724. Thus, a search of the class and subclass for one set of claims can be carried out at the same time for the other set of claims. In fact, the MPEP is clear on this point. "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of **separate classification** or status in the art, or a different field of search as defined in MPEP § 808.02." MPEP 803 (8th Ed. latest revision May 2004). There is no separate classification of the groups. Hence, there is no serious burden to search all claims.

Thus, in view of M.P.E.P. § 803, all the subject matter in Class/subclass 514/724 should be examined together. As proof that the search will not require additional work, the examiner's own categorization of the claims places them in the same class and subclass. So by searching only ONE class and subclass the Office conducts a search for them all.

Even, if the subject matter of these groups are distinct inventions, it would not be a "serious burden" on the Examiner to search these groups in this application. Indeed, as applicants have explained above, the burden of searching these groups together would be no greater than that for Group I alone.

In summary, applicants have demonstrated that the subject matter of the claims of Groups I-II should be examined in the same application. Applicants request, therefore, that

the restriction requirement be withdrawn and that all of claims 1-19 be searched and examined together.

Moreover, applicants are not aware of any references which teach the presently claimed products. For this reason, applicants submit that all claims are not in condition for allowance, early notice of which would be appreciated.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

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